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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|------------------------------------|----------------------|---------------------|------------------|
| 10/590,651 | 05/31/2007 | Ludwig Baux | 1032475-000019 | 2156 |
| | 7590 03/22/201 INGERSOLL & ROOI | EXAMINER | | |
| POST OFFICE | BOX 1404 | NANDIGAMA, KRISHNA | | |
| ALEXANDRIA, VA 22313-1404 | | | ART UNIT | PAPER NUMBER |
| | | | 4124 | |
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| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 03/22/2011 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com offserv@bipc.com

| | Application No. | Applicant(s) | | | | |
|--|---|--|--|--|--|--|
| | 10/590,651 | BAUX ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | KRISHNAMACHARY NANDIGAMA | 1657 | | | | |
| The MAILING DATE of this communication ap Period for Reply | pears on the cover sheet wi | th the correspondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailling date of this communication. - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNIC 136(a). In no event, however, may a re will apply and will expire SIX (6) MON' e, cause the application to become AB. | CATION. Seply be timely filed THS from the mailing date of this communication. ANDONED (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | <u>_</u> . | | | | | |
| 2a) This action is FINAL . 2b) This | ☐ This action is FINAL . 2b)☐ This action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) ☑ Claim(s) <u>1-20</u> is/are pending in the application 4a) Of the above claim(s) is/are withdra 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☑ Claim(s) <u>1-20</u> are subject to restriction and/or | wn from consideration. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examine | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the | | ` ' | | | | |
| Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex | · | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Burea * See the attached detailed Office action for a list | ts have been received. ts have been received in Apority documents have been tu (PCT Rule 17.2(a)). | oplication No received in this National Stage | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) | 4) ☐ Interview S | ummary (PTO-413) | | | | |
| 2) Notice of Preferences Cried (PTO-692) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | Paper No(s |)/Mail Date Iformal Patent Application | | | | |

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DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-6, drawn to a method for detecting Cytochrome C in a given biological sample with a redox couple (s) that include oxidizing agent (s).

Group 2, claim(s) 7-20, has drawn to a test kit to detect Cytochrome C in a given biological sample with a redox couple (s) that includes oxidizing agent (s).

- 2. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:
- 3. The bridge that links Group I and II in the claimed inventions is the detection of Cytochrome c in the presence of its oxidizing agent, Cytochrome c oxidase enzyme, and there is no novel technical feature is visible in the invention. Lucile Smith's (Spectrophotometric Assay of Cytochrome c Oxidase, Pages 427-434 in the book Methods of Biochemical Analysis, Volume II, 2006) prior art, and other references therein, recites that cytochrome c along with its oxidizing agent, cytochrome c oxidase enzyme, are ubiquitously present in mammalian tissues, yeast and higher plants; it further recites that the rate of oxidation of cytochrome c (also called ferrocytochrome c) in the presence of oxygen and reducing agent specific for cytochrome c can be

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measured spectrophotometrically. However, in the prior art (Deuk-Seok Yang et al, Korean Biochem. J. Volume 21, No1, Pages 9-17, 1988), Deuk-Seok Yang et al teaches that the inner and the outer membrane of mitochondrion and the inner membrane component were assayed in terms of 340 nm absorption of the NADH oxidation systems (Fig 6, page 14). As showed in the figure 1, page 12, a preliminary test exemplified that no NADH oxidation occurred in the absence of the mitochondria but the reaction occurred upon the addition of them. It infers that as claimed in Groups I and II, without the presence of detectable levels of Cytochrome c in a given biological sample of mitochondrion, the redox couple (s) do not oxidize NADH. Deuk-Seok Yang et al recite that the measurement of oxidized NADH and thus the detection method of Cytochrome c by absorption spectrophotometry at 340 nm "Lacks Novelty &Inventive Step.". Therefore, the technical feature linking the inventions of groups I & II does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

- 4. Accordingly, Groups I and II are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.
- 5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does

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not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof.

Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case.

Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- 6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventions is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 7. The examiner has required restriction between product and process claims.

 Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise

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require all the limitations of the allowable product claim will be considered for rejoinder.

<u>All</u> claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISHNAMACHARY NANDIGAMA whose telephone number is (571)270-1015. The examiner can normally be reached on Monday thru Friday, 7:30 AM to 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnamachary Nandigama/ Patent examiner Art Unit 1657

/Anne Marie Grunberg/ Supervisory Patent Examiner, Art Unit 1638